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(11)

**EP 0 998 958 B1**

(12)

**EUROPEAN PATENT SPECIFICATION**

(45) Date of publication and mention  
of the grant of the patent:  
03.08.2005 Bulletin 2005/31

(51) Int Cl.7: **A61N 1/36**(21) Application number: **99120925.5**(22) Date of filing: **02.11.1999****(54) System for optimized brain stimulation**

System für eine optimierte Gehirnstimulation

Système pour une stimulation cérébrale optimisée

(84) Designated Contracting States:  
**DE FR**

(30) Priority: **05.11.1998 US 185490**

(43) Date of publication of application:  
**10.05.2000 Bulletin 2000/19**

(73) Proprietor: **Medtronic, Inc.**  
**Minneapolis, Minnesota 55432-5604 (US)**

(72) Inventor: **Gielen, Frans L.H.**  
**6251 NE Eckelrade (NL)**

(74) Representative: **Hughes, Andrea Michelle et al**  
**Frank B. Dehn & Co.,**  
**European Patent Attorneys,**  
**179 Queen Victoria Street**  
**London EC4V 4EL (GB)**

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**WO-A-95/21591**  
**US-A- 5 065 083**

**WO-A-97/39796**  
**US-A- 5 702 429**

**EP 0 998 958 B1**

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1

EP 0 998 958 B1

2

**Description**

[0001] This invention lies in the field of systems for brain stimulation and recording of brain activity and, more particularly, systems for placement of the lead for stimulating and/or recording at an optimized physiological brain target, for the treatment of conditions such as movement disorders.

[0002] Deep Brain Stimulation (DBS) has been found to be successful in treating a variety of brain-controlled disorders, including movement disorders. Generally, such treatment involves placement of a DBS type lead through a burr hole drilled in the patient's skull, followed by placement of the lead and then applying appropriate stimulation through the lead to the physiological target. The placement portion of the treatment is very critical, and has been the subject of much attention and research. In particular, finding the deep brain target and then placing the permanent lead so that it efficiently stimulates such target is very important. See, for example, U.S. Patent No. 6,011,998, filed January 20, 1998, Gielen et al, which deals with the localization procedure in functional stereotactic brain surgery, i.e., the initial probing to find the optimum site for delivering the stimulation.

[0003] US 5,702,429 discloses a neural stimulation device comprising an implanted lead having a stimulation electrode and a recording electrode.

[0004] WO 97/39796 discloses apparatus for brain stimulation by means of an implantable signal generator and electrode.

[0005] Finding the optimal physiological target in deep brain stimulation implants for the treatment of movement disorders is a particularly complicated task. This is especially true for the treatment of symptoms which cannot be tested at the operating table during lead implant. For instance, it is impossible to test walking and postural stability in Parkinson's Disease (PD) patients during DBS lead implant. Two other major PD symptoms, Rigidity and Akinesia, are also considered difficult to evaluate quantitatively during DBS lead implant. Thus far, no reliable quantitative evaluation procedures exist that can be performed during the surgical DBS implant procedure for these major symptoms.

[0006] A recent procedure has been suggested which allows post-operative quantitative testing of muscle function in PD. See Pascual-Leone, Rapid Rate Transcranial Magnetic Stimulation (rTMS) in Movement Disorders; Movement Disorders, Vol 11, Suppl. #1, pp.23, 1996. In this procedure, trans-cranial magnetic stimulation of the motor cortex is used to show that the brain is able to control muscle movements in a normal way when and if the DBS electrode is implanted in the optimal physiological position in the Globus Pallidum Internae (GPI) and electrical stimulation with the appropriate parameters is applied through the DBS electrode. Thus, it was shown that those areas of the motor cortex (MC) which are involved in the control of movement in the

muscle of the thumb can only be activated if the appropriate DBS stimulation is concurrently applied to the correct part of the GPI.

[0007] Based on this finding, it is reasonable that an improved procedure could be utilized for optimizing the implant position of the DBS electrode(s) in the GPI or other neuro-modulation target for treating disorders, and particularly movement disorders, by means of deep brain stimulation. Thus, if postural instability of the patient is a major PD symptom, one might be able to find the optimal physiological target for the DBS electrode by seeing when trans-cranial magnetic stimulation of the motor cortex achieves optimal control movement of the leg muscles. However, this magnetic stimulation procedure is not suitable for intra-operative use, i.e., for testing lead position while the lead is stereotactically held. The applied very fast changing and very strong magnetic fields may interact with the DBS electrode in a comparable way as suggested for MRI imaging procedures, which is contra-indicated for DBS patients. Further, the trans-cranial magnetic stimulation coil cannot be accessed to the relevant sites of the brain when the DBS lead is being held by the stereotactic equipment. This means that the Leone procedure is not directly suggested for use in evaluating the excitability of the relevant motor cortex areas during lead implant. Thus, while the prior art procedure is appropriate for certain post-surgical testing because it is non-invasive, it is not suggested for intra-operative use.

[0008] The continued need in the art is a system and procedure that can be utilized during surgery when the DBS lead is being implanted, to determine when it has been placed in the optimal position for stimulation therapy of the patient's particular disorder, or for recording of brain activity. In general terms, the aim is a system for stimulation of the GPI or other neuro-stimulation target, and a feedback target such as the MC. A key to this invention is the recognition that during surgery, there is no need for a non-invasive way of stimulating the feedback target. The invention, rather, provides apparatus for testing for the optimal DBS electrode position during the invasive surgery, and as part of the localization test procedure that is required in any event, enabling a reliable determination of optimal lead placement before permanent lead implant and close of surgery.

[0009] A primary object of this invention is to provide a system for determining with a test lead or permanent lead when a brain electrode is positioned optimally so during stimulation of the brain target normal patient excitability of a feedback target such as the motor cortex achieves the desired result, e.g., the desired body movement of a patient with a movement disorder. Alternatively, another object is to provide an improved capacity to record brain activity.

[0010] The invention takes advantage of the fact that during DBS lead implant, the patient's brain is already subject to an invasive procedure. This being the case, both the neuro-modulation target and the feedback tar-

3

EP 0 998 958 B1

4

get can be readily stimulated during surgery. Thus, in the case of movement disorders involving the motor cortex, the stimulation of the motor cortex concurrently with the GPI need not be limited to a non-invasive technique.

[0011] In order to achieve the above objects, the invention provides a brain stimulation system, comprising a brain stimulator or device and lead means for placement of electrodes at predetermined positions within a patient's brain, said brain stimulator device having first pulse means for generating feedback pulses for stimulating a feedback target in the patient's brain and second pulse means for generating DBS pulses for stimulating a neuro-modulation target in said patient's brain; and said lead means being connected to said device for conducting said pulses from said device to said respective targets, said lead means comprising a DBS electrode and a conductor for conducting said DBS pulses from said second pulse means to said DBS electrode, a feedback electrode and a conductor for conducting said feedback pulses from said first pulse means to said feedback electrode, and said DBS and feedback electrodes being positioned on said lead means relative to each other so that when said DBS electrode is positioned at said neuro-stimulation target said feedback electrode is positioned at said feedback target.

[0012] By varying the position of the DBS electrodes, and repeatedly stimulating both the DBS target and the feedback target, and observing the relevant patient body movement or other reaction, the optimal DBS target location can be found. Also, either or both of the electrodes can be used for recording brain activity.

[0013] After the finding of the optimal DBS target location, the test lead is removed and a permanent lead positioned so that the DBS electrode(s) is located at the optimal target position. The permanent lead also preferably is aligned along the linear trajectory which includes both the neuro-modulation and the feedback targets, and carries electrodes for stimulating or recording at both targets, thereby enabling post-operative testing. The system preferably includes a generator device with dual stimulus pulse channels for providing stimuli with appropriate parameters for stimulating the respective targets, and sense channels for amplifying and processing detected brain signals.

[0014] Preferred embodiments will now be described, by way of example only, with reference to the drawings.

Figure 1 is a diagrammatic view of a patient's skull and the target path or paths taken to stimulate target areas of the brain in accordance with use of the system of this invention, and/or to record brain activity at the dual target sites.

Figure 2 is a schematic diagram showing a system in accordance with this invention, including an implantable stimulator/recorder device, and a test or permanent lead designed to enable dual stimulation of different brain sites and/or recording of brain signals from such sites.

Figure 3A is a diagrammatic view showing a brain stimulating lead and a slidable sleeve with a window; Figure 3B is a diagrammatic view showing the sleeve in position over the lead portion which carries electrodes for stimulating the motor cortex, thereby enabling adjustment of the location of an effective electrode on the lead for stimulating the motor cortex at the same time that the physiological brain target is stimulated.

Figure 4 is a flow diagram illustrating the primary steps taken in using the system of this invention to determine whether and when the brain lead has been optimally positioned in a patient's brain in order to treat a movement disorder or the like.

[0015] Referring now to Figure 1, there is shown a diagram of a patient's head, with burr holes BH-A and BH-B shown drilled through the patient's skull to allow entry beneath the dura. While Figure 1 presents an illustration of the specific MC/GPI embodiment, it is to be understood that the principles involved are equally applicable to other targets, as discussed above. A normal trajectory would be that indicated through the hole BH-A, along trajectory A, to the GPI. However, as indicated, the motor cortex MC is not along this line. In order to have a single one-dimensional trajectory which will involve both the GPI and the MC, burr hole BH-B is utilized, to provide a trajectory as indicated along indicated line B. It is to be noted that skull sizes vary from patient to patient, and that accordingly the distance from the GPI target and the MC target will be variable, perhaps in the range of up to 2 cm from patient to patient. For this reason, the lead of this invention preferably includes an adjustable electrode location for stimulating the feedback target, e.g., the MC, when the distal electrodes are in place for stimulating the GPI or other brain target.

[0016] Referring now to Figure 2, there is shown a diagram of a stimulator/recorder device 30 coupled to and used in connection with a lead 40. Stimulator device 30 may be, for example, a Medtronic Model 3628, or a modification thereof; and the lead may be a modification of Medtronic InterStim Model 4300 or Medtronic DBS Lead Model 3387. As indicated, the stimulator device contains two pulse generation channels, channel 1 indicated at 32 and channel 2 at 34. Each of these channels is controlled by control block 35, which may appropriately utilize a microprocessor and/or other control and timing circuitry. The lead proximal end 41 is connected to the outputs of the device 30. Channel 1 connects to one or more lead conductors which provide electrical connection to distal electrodes indicated at 46 near the lead distal end 42. These electrodes are positioned at the neuro-modulation target, e.g., the GPI. The pulses generated by channel 1 and delivered to the deep brain location are, for example, pulses of 60-120  $\mu$ s pulse width, typically delivered at a rate in the range of about 50-250 Hz, and with a pulse amplitude of about 1-10 v. The signals delivered by channel 2 are connected through to

5

EP 0 998 958 B1

6

electrode 44, which is shown positioned proximally from electrodes 46, and at a distance in the neighborhood of 3-8 cm from the distal electrodes 46, depending on the application. For example, for the MC/GPI embodiment, the positioning of electrode 44 is designed to place it proximate to the motor cortex when the distal electrodes 46 are positioned at the GPI brain target. The pulses delivered by channel 2 are, e.g., pulses of a width 1-10 ms, delivered at a rate of 1 to 5 Hz and with a voltage in the range of 1-10 v. Signals received from the electrodes are processed at sense channels 37,38 and stored at 39.

[0017] Referring now to Figures 3A and 3B, there is shown one arrangement for adjusting the position of electrode 44, to provide for stimulation of the MC concurrently with stimulation of the GPI. In this embodiment, electrode 44 is suitably comprised of a series of smaller ring electrodes, as indicated at 48, the purpose of this design being to achieve a greater lead flexibility. Alternatively, but at the cost of some flexibility, the electrode 44 may be one integral ring electrode, providing a large surface extending around the tubular body 43 of lead 40. Shown above the lead portion carrying electrode 44 is a sliding tubing, or sleeve 50, being a hollow tubing having an inner diameter adapted to just fit over the outer diameter of lead body 43. Tubing 50 is made of an electrically insulative material coating 51, except at a window portion 52 of predetermined length. The tubing 50 extends proximally a sufficient distance so that it can be manipulated, i.e., slid along the lead 43 so as to position the window portion 52 relative to the lead. In Figure 3B, the tubing is illustrated as having been slid down to register with a portion of the rings 48, providing an electrode which is adjustable along the axis of the lead by positioning of the window.

[0018] Referring now to Figure 4, there is illustrated a flow diagram of the primary steps taken in carrying out the procedure of this invention, illustrated with respect to the MC/GPI embodiment. At block 60, the test is initiated by providing a test lead as discussed in connection with Figures 2 through 3B above. Such a test lead is provided with respective MC and GPI electrodes, where the position of the MC electrode is preferably adjustable to account for required patient variations in inter-electrode distance, as discussed in connection with Figure 1. The location of the GPI and the MC are then preliminarily determined, as indicated at 62. The approximate location of the GPI can be determined non-invasively; a more exact location of the GPI target can be determined as discussed in the above referenced U. S. Patent No. 6,011,998. The location of the MC can be determined, e.g., by trans-cranial magnetic stimulation. With this information having been obtained, the desired one-dimensional trajectory through the two targets is known. Next, at 64, a burr hole is drilled to provide entry through the skull for the desired linear trajectory. Note that if a first burr hole is drilled in order to perform the initial localization, it can be used for placement of a sep-

arate lead to the GPI, as discussed above. Then, as indicated at 65, the test lead is stereotactically introduced along the trajectory, and the distal DBS electrode positioned in the area of the GPI. After that, at 66, the position of the MC electrode 44 is adjusted, e.g., in the manner suggested by the discussion of Figures 3A, B. The positioning of electrode 44 with respect to the MC will, of course, depend upon what body portion is to be tested or treated. After this, at 68, the two targets are stimulated, and the relevant body movement, or lack thereof, is noted. This provides the feedback for determining when the DBS electrode has been optimally located. Also, at 68, brain activity at the two sites can be recorded.

[0019] At 70, it is determined whether the DBS electrode complex 46 is optimally located. If no, which would include a state of uncertainty, the position of the DBS electrode is adjusted, as shown at 72, and then the stimulation is repeated, as indicated by the branch that loops back to 68. When the physician is satisfied that an optimal position has been found, the test is concluded, and the permanent lead is implanted, as indicated at 74. The lead is then attached to the generator device, and the patient is chronically stimulated, as indicated at 76.

As mentioned above, by providing a permanent lead that also has an MC electrode, and is placed along the trajectory that encompasses both targets, subsequent tests can be conducted. Further, brain signal recordings can be obtained from the electrode sites, either concurrently, or at one site during stimulation of the other site.

[0020] There is thus provided a system for stimulating or recording at dual sites in a patient's brain, e.g., a feedback site such as the motor cortex, and a deep brain or neuro-modulation site such as the GPI. While the preferred embodiment has been presented as a single lead, either a test or permanent lead, it is to be understood that the invention can likewise be practiced by insertion of two leads, e.g., one for positioning of an electrode at the motor cortex and one for positioning of an electrode at the GPI. As used herein, the term "electrode" means either a single electrode or a plurality of electrodes, as illustrated in Figures 2 and 3A.

#### Claims

1. A brain stimulation system, comprising a brain stimulator device (30) and lead means (40) for placement of electrodes at predetermined positions within a patient's brain,

said brain stimulator device having first pulse means (32) for generating feedback pulses for stimulating a feedback target in the patient's brain and second pulse means (34) for generating deep brain stimulation DBS pulses for stimulating a neuro-modulation target in said patient's brain; and  
said lead means (40) being connected to said

7

EP 0 998 958 B1

8

device for conducting said pulses from said device to said respective targets, characterised in that said lead means comprising a DBS electrode (46) and a conductor for conducting said DBS pulses from said second pulse means to said DBS electrode, a feedback electrode (44) and a conductor for conducting said feedback pulses from said first pulse means to said feedback electrode, and said DBS and feedback electrodes being positioned on said lead means relative to each other so that when said DBS electrode is positioned at said neuro-stimulation target said feedback electrode is positioned at said feedback target.

2. The system as described in claim 1, wherein said lead means is a single lead (40), and said DBS electrode (44) is positioned near the lead distal end and said feedback electrode is positioned about 3-8 cm from said DBS electrode, whereby said lead can be inserted into the patient's brain along a predetermined path to position said electrodes at said respective feedback and neuro-modulation targets.
3. The system as described in claim 2, wherein said lead comprises adjusting means for adjusting the position of said feedback electrode to be positioned at the patient's motor cortex when said DBS electrode is positioned at said patient's GPI.
4. The system as described in claim 3, wherein said lead has a lead body, and said adjusting means comprises a slidable tubing (50) having a window (52), said tubing being slidable over said lead body to expose said feedback electrode at a desired position relative to the motor cortex.
5. The system as described in claim 4, wherein said feedback electrode has an effective surface area larger than the area of said window.
6. The system as described in any preceding claim, wherein said first pulse means comprises MC generator means for generating pulses at a rate of about 1-5 Hz for delivery to the patient's motor cortex, and parameter means for controlling said generated pulses to have a duration of about 1-10 ms and a voltage of about 1-10 Volts.
7. The system as described in any preceding claim, wherein said second pulse means comprises DBS target means for generating pulses at a rate of about 50-250 Hz, and parameter means for controlling generation of said pulses to have a duration in the range of about 60-120  $\mu$ s and a voltage in the range of about 1-10 Volts.
8. The system as described in any preceding claim,

wherein said brain stimulator device further comprises means (37, 38) for receiving signals from at least one of said electrodes and means (39) for recording such signals.

#### Patentansprüche

1. Gehirnstimulationssystem mit einer Gehirnstimulatorvorrichtung (30) und einem Leitungsmittel (40) zum Anordnen von Elektroden an vorgegebenen Positionen innerhalb des Gehirns eines Patienten, wobei die Gehirnstimulatorvorrichtung ein erstes Impulsmittel (32) zum Erzeugen von Rückkopplungsimpulsen zum Stimulieren eines Rückkopplungstargets im Gehirn des Patienten und ein zweites Impulsmittel (34) zum Erzeugen tiefer Gehirnstimulations-DBS-Impulse zum Stimulieren eines Neuromodulationstargets im Gehirn des Patienten aufweist, und das Leitungsmittel (40) mit der Vorrichtung verbunden ist, um die Impulse von der Vorrichtung zu den jeweiligen Targets zu leiten, dadurch gekennzeichnet, dass das Leitungsmittel eine DBS-Elektrode (46) und einen Leiter zum Leiten der DBS-Impulse von dem zweiten Impulsmittel zu der DBS-Elektrode, eine Rückkopplungselektrode (44) und einen Leiter zum Leiten der Rückkopplungsimpulse von dem ersten Impulsmittel zu der Rückkopplungselektrode aufweist und die DBS- und die Rückkopplungselektrode so in Bezug zueinander an dem Leitungsmittel positioniert sind, dass die Rückkopplungselektrode an dem Rückkopplungstarget positioniert ist, wenn die DBS-Elektrode an dem Neurostimulationstarget positioniert ist.
2. System nach Anspruch 1, wobei das Leitungsmittel eine einzige Leitung (40) ist und die DBS-Elektrode (44) in der Nähe des distalen Endes der Leitung positioniert ist und die Rückkopplungselektrode etwa 3 - 8 cm von der DBS-Elektrode positioniert ist, wodurch die Leitung entlang einem vorgegebenen Weg in das Gehirn des Patienten eingeführt werden kann, um die Elektroden an dem jeweiligen Rückkopplungstarget und dem jeweiligen Neuromodulationstarget zu positionieren.
3. System nach Anspruch 2, wobei die Leitung ein Einstellmittel zum Einstellen der Position der Rückkopplungselektrode aufweist, die an der motorischen Hirnrinde des Patienten zu positionieren ist, wenn die DBS-Elektrode am GPI des Patienten positioniert ist.
4. System nach Anspruch 3, wobei die Leitung einen Leitungskörper aufweist und das Einstellmittel el-

9

EP 0 998 958 B1

10

nen verschiebbaren Schlauch (50) mit einem Fenster (52) aufweist, wobei der Schlauch über den Leitungskörper geschoben werden kann, um die Rückkopplungselektrode an einer gewünschten Position in Bezug auf die motorische Hirnrinde freizulegen.

5. System nach Anspruch 4, wobei die Rückkopplungselektrode eine wirksame Oberfläche aufweist, die größer ist als die Fläche des Fensters.
6. System nach einem der vorstehenden Ansprüche, wobei das erste Impulsmittel ein MC-Generatormittel zum Erzeugen von Impulsen mit einer Frequenz von etwa 1 - 5 Hz zur Abgabe an die motorische Hirnrinde des Patienten und ein Parameternittel zum Steuern der erzeugten Impulse, so dass sie eine Dauer von etwa 1 - 10 ms und eine Spannung von etwa 1 - 10 Volt haben, aufweist.
7. System nach einem der vorstehenden Ansprüche, wobei das zweite Impulsmittel ein DBS-Targetmittel zum Erzeugen von Impulsen bei einer Frequenz von etwa 50 - 250 Hz und ein Parameternittel zum Steuern der Erzeugung der Impulse, so dass sie eine Dauer im Bereich von etwa 60 - 120  $\mu$ s und eine Spannung im Bereich von etwa 1 - 10 Volt haben, aufweist.
8. System nach einem der vorstehenden Ansprüche, wobei die Gehirnstimulatorvorrichtung weitere Mittel (37, 38) zum Empfangen von Signalen von mindestens einer der Elektroden und Mittel (39) zum Aufzeichnen solcher Signale aufweist.

#### Revendications

1. Système de stimulation cérébrale, comportant un dispositif de stimulation cérébrale (30) et des moyens de branchement (40) pour placer des électrodes à des positions prédéterminées dans le cerveau d'un patient, ledit dispositif de stimulation cérébrale ayant des premiers moyens d'impulsions (32) pour générer des impulsions de rétroaction pour stimuler une cible de rétroaction dans le cerveau du patient et des seconds moyens d'impulsions (34) pour générer des impulsions de stimulation cérébrale profonde (DBS) pour stimuler une cible de neuro-modulation dans ledit cerveau de patient; et lesdits moyens de branchement (40) étant connectés audit dispositif pour conduire lesdites impulsions à partir dudit dispositif jusqu'auxdites cibles respectives, caractérisé en ce que lesdits moyens de branchement comportent une électrode DBS (46) et un conducteur pour conduire lesdites impulsions DBS à partir desdits seconds moyens d'impulsions jusqu'à ladite électrode DBS, une électro-

de de rétroaction (44) et un conducteur pour conduire lesdites impulsions de rétroaction à partir desdits premiers moyens d'impulsions jusqu'à ladite électrode de rétroaction, et lesdites électrodes DBS et de rétroaction étant positionnées sur lesdits moyens de branchement l'une par rapport à l'autre de sorte que lorsque ladite électrode DBS est positionnée au niveau de ladite cible de neuro-stimulation, ladite électrode de rétroaction est positionnée au niveau de ladite cible de rétroaction.

2. Système selon la revendication 1, dans lequel lesdits moyens de branchement sont un branchement unique (40), et ladite électrode DBS (44) est positionnée près de l'extrémité distale de branchement et ladite électrode de rétroaction est positionnée environ à 3 à 8 cm par rapport à ladite électrode DBS, ainsi ledit branchement peut être inséré dans le cerveau du patient le long d'un trajet prédéterminé pour positionner lesdites électrodes au niveau desdites cibles de rétroaction et de neuro-modulation respectives.
3. Système selon la revendication 2, dans lequel ledit branchement comporte des moyens de réglage pour régler la position de ladite électrode de rétroaction de manière à la positionner au niveau du cortex moteur du patient lorsque ladite électrode DBS est positionnée au niveau du Globus Pallidum Internae (GPI) du patient.
4. Système selon la revendication 3, dans lequel ledit branchement a un corps de branchement, et lesdits moyens de réglage comportent un tube coulissant (50) ayant une fenêtre (52), ledit tube pouvant coulisser sur ledit corps de branchement pour exposer ladite électrode de rétroaction à une position voulue par rapport au cortex moteur.
5. Système selon la revendication 4, dans lequel ladite électrode de rétroaction a une surface effective qui est supérieure à la surface de ladite fenêtre.
6. Système selon l'une quelconque des revendications précédentes, dans lequel lesdits premiers moyens d'impulsions comportent des moyens de génération MC pour générer des impulsions à une fréquence d'environ 1 à 5 Hz à appliquer au cortex moteur du patient, et des moyens de paramétrage pour commander lesdites impulsions générées pour qu'elles aient une durée d'environ 1 à 10 ms et une tension d'environ 1 à 10 volts.
7. Système selon l'une quelconque des revendications précédentes, dans lequel lesdits seconds moyens d'impulsions comportent des moyens de cible DBS pour générer des impulsions à une fréquence d'environ 50 à 250 Hz, et des moyens de

11

EP 0 988 950 B1

12

paramétrage pour commander la génération d'edites impulsions pour qu'elles aient une durée dans la plage d'environ 60 à 120  $\mu$ s et une tension dans la plage d'environ 1 à 10 volts.

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8. Système selon l'une quelconque des revendications précédentes, dans lequel ledit dispositif de stimulation cérébrale comporte de plus des moyens (37, 38) pour recevoir des signaux provenant d'au moins l'un parmi lesdites électrodes et lesdits moyens (39) pour enregistrer ces signaux.

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EP 0 998 958 B1

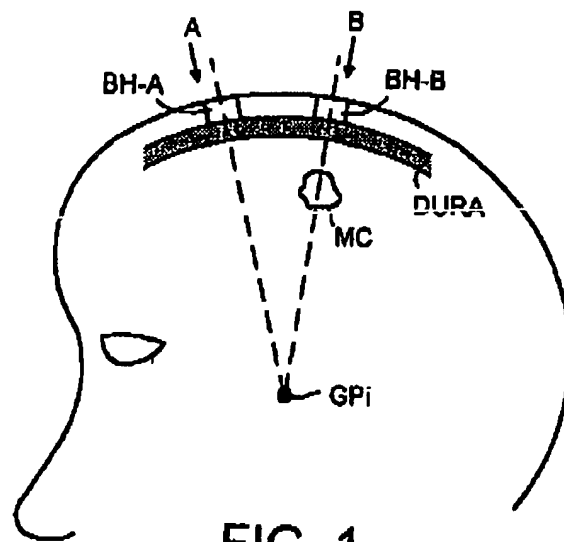


FIG. 1

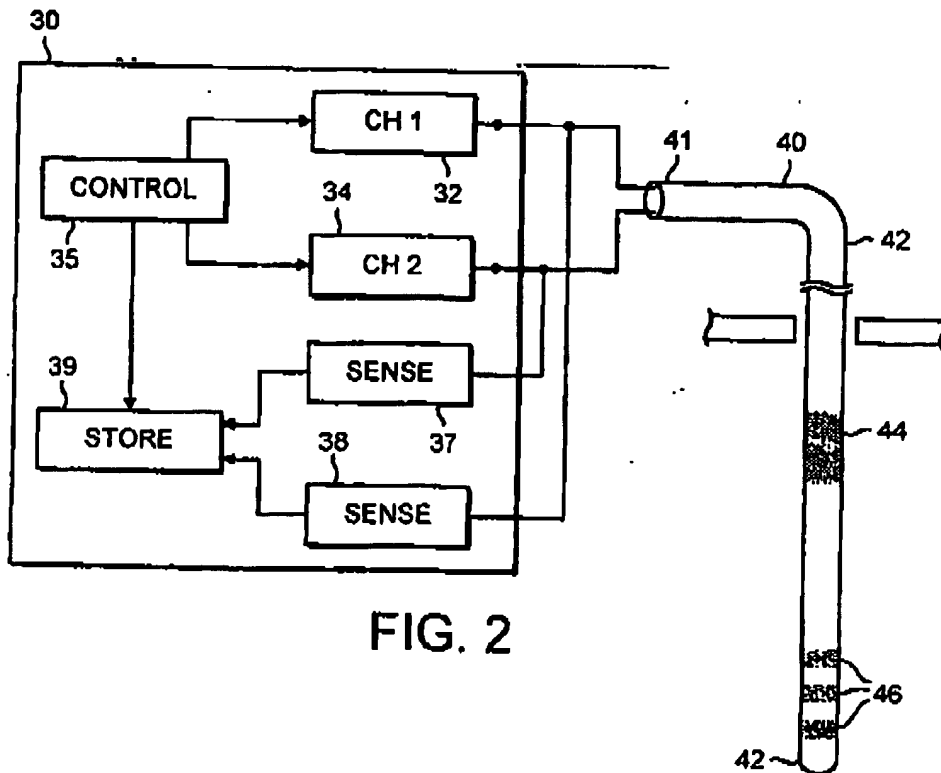


FIG. 2



EP 0 998 958 B1

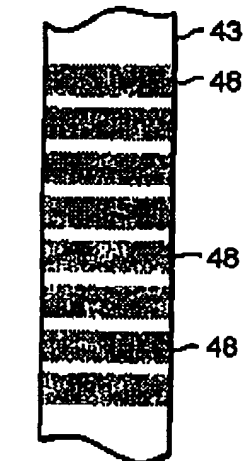
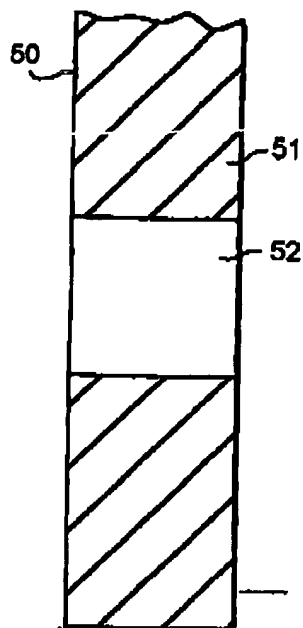


FIG. 3A

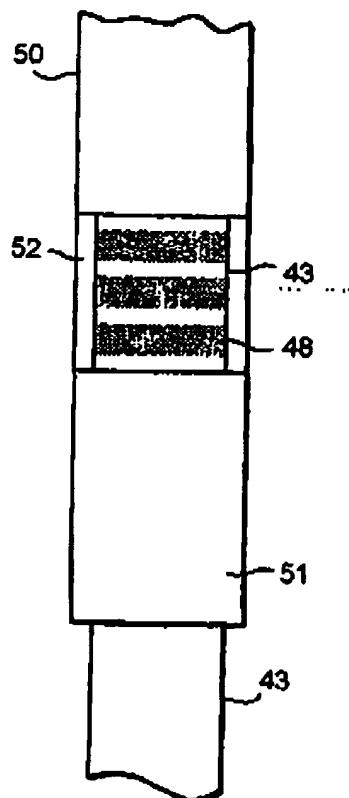
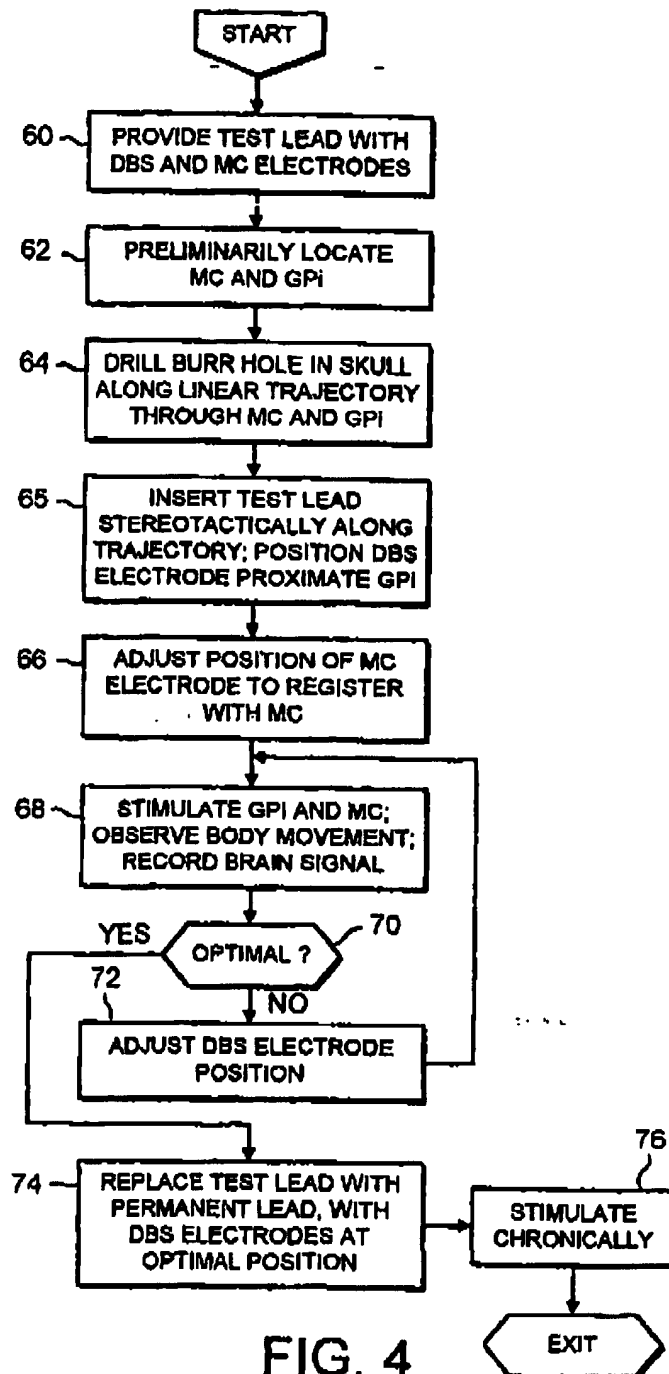


FIG. 3b

EP 0 998 958 B1



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